CliChemH
Semi-auto Chemistry Analyzer
User's Manual

BGT BioGenTechnologies GmbH
Von-Langen-Weg 10
D-48565 Steinfurt
Tel.: 02551 / 4090
Fax.: 02551 / 1298
Web: www.biogentechnologies.de
E-Mail: info@biogentechnologies.de

Rev: **2.5e**

CONTENTS

HOW TO USE THE MANUAL **3**

SAFETY PRECAUTIONS AND POTENTIAL HAZARDS **4**

CHAPTER 1 A BRIEF DESCRIPTION **8**

1.1 INSTALLATION 8
1.1.1 Unpacking *8*
1.1.2 Instruments location *8*
1.1.3 Power requirements *9*
1.1.4 Connect the instrument to AC power *9*
1.1.5 Paper Installation *9*
● *Set the screen in properly position* *10*
1.1.6 Flow cell and cuvette system *10*
1.2 SYSTEM OVERVIEW 11
1.2.1 Front View *11*
1.2.2 Keyboard Functions *11*
1.2.3 Rear view *12*
1.2.4 Flow cell and cuvette *13*
1.2.5 Lamp and sipper pump *13*

CHAPTER 2 OPERATING PROCEDURES **15**

2.1 POWERING ON 15
2.2 BASIC OPERATING 16
2.2.1 Mouse *16*
2.2.2 Keyboard(option) *16*
2.2.3 Soft-keyboard *16*
2.3 MAIN MENU AND SYSTEM PARAMETERS SETTING 16
2.4 PROGRAMMING TEST PARAMETERS 18
2.4.1 Modifying preprogram *18*
2.4.2 Programming a new assays *19*
2.4.3 Calibration parameter *19*
2.4.4 Control parameter *19*
2.4.5 Selecting a Mode *20*
2.4.6 Save the Change *21*
2.4.7 Return *21*
2.5 PERFORM TESTS 21
2.5.1 Test procedure menu *21*
2.5.2 Perform *22*
2.5.3 Changing test *23*

CHAPTER 3 CALIBRATION BY STANDARD **24**

3.1 GENERAL 24
3.2 PROGRAM CALIBRATION 24

3.3 PERFORM LINEAR TESTS 24
3.4 PERFORM THE CALIBRATION OF NON LINEAR TESTS 25
3.5 LIST CALIBRATION 25

CHAPTER 4 CONTROL 27

4.1 GENERAL 27
4.2 PROGRAM CONTROLS 27
4.3 MEASUREMENT OF CONTROLS 27
4.4 LIST CONTROLS 27

CHAPTER 5 REPORT 29

5.1 SUMMARY 29
5.2 PRINT BY PATIENT 29
5.3 PRINT BY TEST 32
5.4 HISTORY RECORDS 32

CHAPTER 6 REMOTE SERVICE 33

CHAPTER 7 CLOSE SYSTEM 33

CHAPTER 8 MAINTENANCE 34

8.1 GENERAL 34
8.2 CLEANING THE OUTSIDE 34
8.3 CLEAN PROCEDURE FOR THE FLOW CELL 34
8.3.1 Washing when Changing tests 34
8.3.2 Washing twice a day 34
8.3.3 Closing the system by the closing procedure 35
8.4 REPLACEMENT THE LAMP 35
8.5 REPLACEMENT OF THE INTERNAL TUBING 35
8.6 REPLACEMENT THE FUSE 35
8.7 TROUBLE SHOOTING 35
8.8 THE INSTRUMENT'S DISASSEMBLY 36

APPENDIX I: GENERAL SPECIFICATIONS 38

APPENDIX II: SERIAL CONNECTION PROTOCOL 39

How to use the manual

General

Thank you to be the user of CliChemH.

This manual is a user's guide for CliChemH Semi-auto Chemistry Analyzer, and contents system installation, operating procedures, System parameters setting and maintenance. We suggest that the user read the manual carefully.

Please read the ext. Printer manual for the system with ext. Printer.

The instruments with different versions or collocations will have some differences in functions.

Symbols description

Symbols in the manual

NOTE!

Notes contain additional information or tips when using the instrument.

ATTENTION! Cautions

Cautions should be followed carefully to ensure your instrument work correctly and to avoid unnecessary personal injury.

Symbols on the instrument

This symbol means that the labeled item is hot while the instrument is in use. Don't touch the labeled item as you could be burnt.

The symbol is labeled on the lamp bracket of optic system.

This means that the labeled item could lead to personal injury and/or damage to the analyzer.

The symbol is labeled beside the power outlet and some external interface.

The symbols for "SERIAL NUMBER", the serial number shall be after or below the symbol, adjacent to it.

The symbol means the product is in vitro diagnostic medical device.

The symbol indicates the manufacturer and its address, after which are shown its name and address.

The symbol indicates EU representatives of the manufacturer and their addresses, after which are shown their names and addresses.

The symbol indicates biological pollution, marked in the part where the instrument contacts the clinical reagent. The symbol appears in black side and yellow background.

The symbol indicates temperature range of the analyzers during storage and transportation.

Safety Precautions and Potential Hazards

General

Before you start installing and working with the analyzer, you should read the safety precautions and regulations shown in this chapter.

Operator Qualification

Please note that the operation with Chemistry analyser should be carried out only by the doctor or clinical inspector who has undergone necessary training provided by the sales agent.

Service Technician Qualification

To install, maintain and repair the instrument, a service technician has to be trained on the instrument by the manufacturer or their representative. A service technician is also expected to be familiar with the normal operation of the instrument as described in the User’s manual and the special operations as described in the service manual.

Electrical

To use analyser safely, pay attention to the following items:

To prevent the risk of electrical shock and/or damage to the instrument **Operator** should not open the white cover of the instrument. Only authorized personnel, for example, **service technicians**, may open the instrument to perform maintenance or repair.

Touching the main board when the power is on may cause severe injury or death. Any problem, please ask for helps from your supplier.

Mechanical

There is no risk presented by the mechanical parts of the instrument when the instrument is closed. If the covers of the instruments are removed, mechanical parts could cause personal injury or the instrument may be damaged if the following advice is not being considered: DO NOT wear loose garments or jewellery that could catch in mechanisms. DO NOT put your fingers/hands into the pathway or any part while the analyzer is in operation. DO NOT attempt mechanical repair unless the instrument is not in operation or OFF.

Lamp

The source lamp becomes extremely hot during operation; never touch the lamp when it is on! Look directly into the light path of the lamp may cause eyes damage, too.

If the lamp needs to be changed, always switch off the lamp by switching off the instrument and then wait until the lamp has cooled down.

Chemical

The operator is responsible for taking all necessary precautions against hazards associated with the use of clinical laboratory chemicals. Specific recommendations for each reagent used with the analyzer are normally found on the manufacturer's package inserts or the on the product information sheets for each chemical. Wipe up any reagent spillage on the instrument immediately.

Biohazardous Materials

As with all vitro diagnostic equipment, patient samples and serum-based quality control (QC) products that are assayed on this system, as well as all waste from the waste container, should be treated as the potentially biohasardous. All materials and mechanical components associated with the sampling and waste system should be handled according to your facility's biohazard procedure. Use the personal protective equipment recommended by your facility when handling any of these components. Detailed recommendations:

- **Samples**

Treat all samples as potentially biohaazardous and infectious. If any sample is spit on the instrument, utilize the correct personal protective equipment (PPE- gloves, lab coat, etc...), wipe it up immediately and clean the contaminated with a disinfectant.

- **Waste solutions and solid wastes**

Avoid direct contact with waste solution and/or solid waste. Both should be handled as potentially biohazardous.

Dispose of waste solution and/or solid waste according to the relevant governmental regulations.

Consult the reagent manufacturer for information on the concentrations of heavy metals and other toxic constituents in each reagent.

- **Biohazardous parts**

Avoid direct contact with the sipper tubing and all parts of the sample flow path. Treat these areas as potentially biohazardous and /or infectious

- **Reagents**

Avoid direct body-contact with reagents. Direct body-contact may result in irritation or damage to your skin. Refer to the manufacturer's reagent kit box and package inserts, or product information sheets for specific instructions.

Avoid direct body-contact with cleaning solution. Direct body-contact amy result in skin irritation or damage. Refer to the manufacturer's kit box and package inserts, or product information sheets for specific instructions.

ATTENTION! Cautions

Require for Samples and Reagents, calibrators and controls.
BGT's Semi-auto Chemistry Analyzer is a Reagent open system. But before the testing, the following items should be noted first.
Generally, all the reagent and samples have to be stored and prepared as per the manufactures' instructions. BGT BioGenTechnologies GmbH do recommend that these reagents should from **the manufactures** with valid **product quality certificate** and **production permission legalized by local government** or from the **valid distributors** appointed by **BGT BioGenTechnologies GmbH** in your country.
Before your test, please check the following.
Check the expiration date of the material
Check if the reagent is stored properly as the requirement. (E.g. cooled or frozen storage before using)
Check for proper programming in parameter setting menu according to the specified reagent instructions.
Check for volume required for each material.
Check for proper and calibrated pipette to prepare the solution.

Additional Precautions

- **Flammables**

Avoid using dangerous flammable material around the instrument.

- **Accuracy/Precision of the Measured Results**

For proper use of the instrument, measure control samples and monitor the instrument during the operation.

An incorrectly measured result may lead to an error in diagnosis, thereby posing a danger to the patient.

Treat all reagents according to the manufacturer’s recommendations. Refer to the reagent kit box and package inserts, or product information sheets for specific instructions.

Make sure that the sample/reagent mixture does not contain any blood clots, dust or other insoluble contaminants. If insoluble contaminants are contained in the sample, correct measuring values may not be obtained.

- **Application**

The instrument is designed for clinical chemistry test analysis using water-soluble samples and reagents.

Please note that other types of analysis may not be applicable to the instrument.

- **Operation and Maintenance**

During operation and maintenance of the instrument, proceed according to the instructors and do not touch any parts of the instrument other than those specified.

Never leave a Reagents/sample mixture in the flowcell for longer than necessary. Always clean the flowcell after a batch of measurement and keep the flowcell filled with distilled water when not in use.

Verify the front covers closed while the instrument in operation.

Avoid touching the mechanism, such as the sipper mechanism inside the instrument, while the instrument is operating. This may cause operation stop or damage the instrument.

Chapter 1 A Brief Description

CliChemH is a universal photometric semi-auto chemistry analyzer. The advanced software based on Windows CE gives the instrument friendly interfaces which meet the individual requirements of clinical chemistry laboratory.

- 47 of the most commonly assays are stored in the flashing RAM of the CliChemH, which enables user can start working right away with the instrument. 130 of assays can be programmed.
- 6 Analytical Modes:
  Endpoint
  Bichromatic
  Liner regression
  Multi-Calibration
  Two-point
  Kinetics
- The user could connect the unit to the PC of clinic lab by RS232 interface.
- Options:
  Keyboard
- Power-off protection, real-time data saving.

1.1 Installation

1.1.1 Unpacking

Carefully unpack the instrument, removing it from its plastic bag. Keep the boxes and packaging material until being assured that nothing is missing, that the unit has no (internal) transport damage and are working properly.

1.1.2 Instruments location

The CliChemH should be located on a flat surface, which is not exposed to heavy vibrations (i.e. centrifuges, etc.) and direct sunlight. The ventilation openings in the bottom plate and at the rear of the instrument should not be blocked.

Note! *Environmental requirements*

Ambient temperature (operating): 15-32 C
Relative humidity: 20% - 85%
Transport and Storage Environment:

Temperature: -25°C ~55°C

Humidity: <93 %

Atmospheric Pressure: 86Kpa ~106Kpa

1.1.3 Power requirements

- AC110V ~AC250V
- 50~60 Hz
- 150W max

1.1.4 Connect the instrument to AC power

Plug the power cord into the instrument. Plug the power cord into an AC electrical wall outlet.

ATTENTION! Cautions

- **AC power outlet must be connected to ground.**
- **Shut (Power) off the power if smog, special smell or special sounds from the inside of the instrument, and contact your supplier.**
- **Hold the connector when you pull off the power cord. Never pull the cord directly.**

1.1.5 Paper Installation

- Remove the paper cover by pulling up at the top end of the cover.
- Unroll about 10 inches of paper and place the roll on the table behind the instrument.
- Feed a cleanly cut edge of the paper from the back into the printer.
- A ragged edge or wrinkled paper will be difficult to load and could cause a paper jam.
- Feed just over 1 inch of paper in and then press the feed paper key several times to feed over 3 inches of paper. Drop the roll of paper into the printer paper well in back.
- Feed the paper through the paper slot of the cover, then close the cover

- **Set the screen in properly position**

Set the screen in properly position.

Figure 1.1

1.1.6 Flow cell and cuvette system

Figure 1.2

- Remove flow cell cover
- Insert the flow cell or cuvette into the flow cell holder
- Make sure the surface with characters of the flow cell is faced to user.

Note!

Keep the surface of the flow cell or cuvette clean. Don't touch it by fingers.

1.2 System overview

1.2.1 Front View

1) Pump cover: Open the cover, user could change the lamp or maintain the pump.
2) Flow cell cover
3) Sample tube
4) Sample button
5) LCD Screen
6) Hot-key
7) Power-on indicator
8) Printer cover

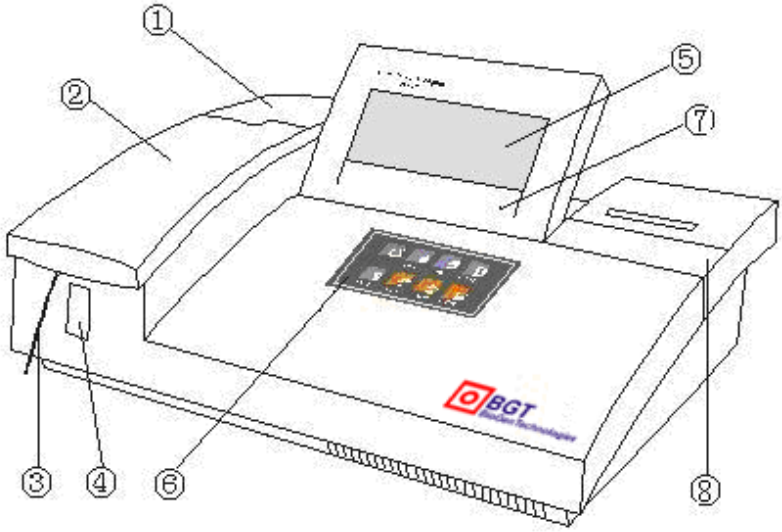


Figure 1.3

1.2.2 Keyboard Functions

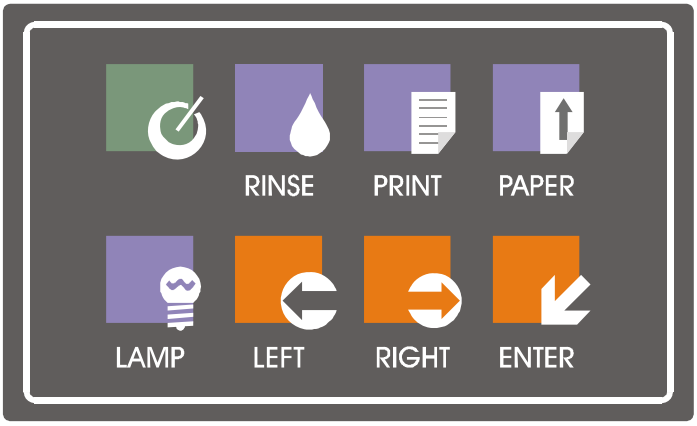


Figure 1.4

1) Soft keyboard: Open or close soft keyboard.

2)

Rinse On, Off: Pressing this control will switch on the sipper pump in a continuous mode, press the key again will stop the pumping action at the end of a complete cycle.

3)

Feed Paper: Control the printer paper for the embedded printer.

4)

Print: Set the printer enable or disable.

5)

Lamp On, Off: Turn off or turn on the Lamp.

6)

Left: This key is used to go backwards in a procedure.

7)

Right: This key will advance the cursor to the next position.

8)

Enter: This key is used to confirm an entry via the keyboard.

1.2.3 Rear view

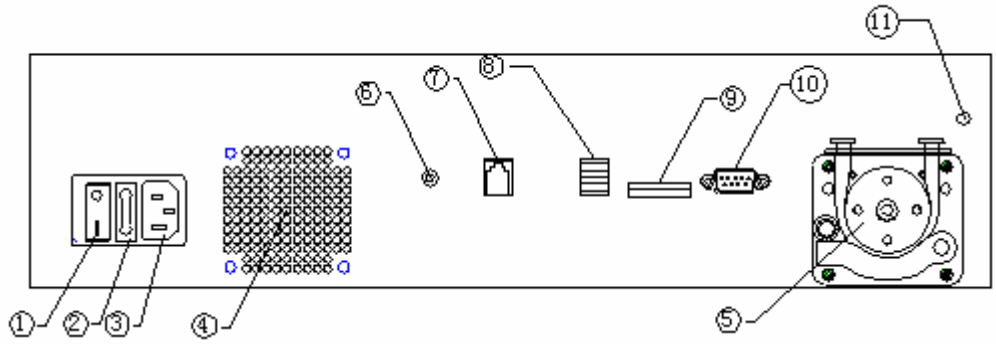


Figure 1.5

1) Power Switch
2) Fuse
3) AC power connector
4) Fan
5) Pump
6) Brightness
7) Lan
8) USB

9) SD Card

10) RS-232 interface

11) Drain Port

1.2.4 Flow cell and cuvette

The following sketches will help you locate and identify the flow cell parts.

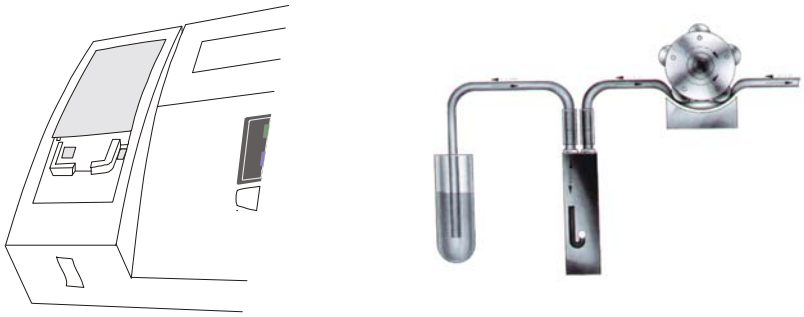


Figure 1.6

1.2.5 Lamp and sipper pump

1) Remove the lamp cover and flow cell cover.
2) The sketches of the lamp and the sipper pump are as show in the following figure1.7, 1.8:

ATTENTION! Cautions

The source lamp becomes extremely hot during operation; never touch the lamp when it is on! Look directly into the light path of the lamp may cause eyes damage, too. If the lamp needs to be changed, always switch off the lamp by switching off the instrument and then wait until the lamp has cooled down.

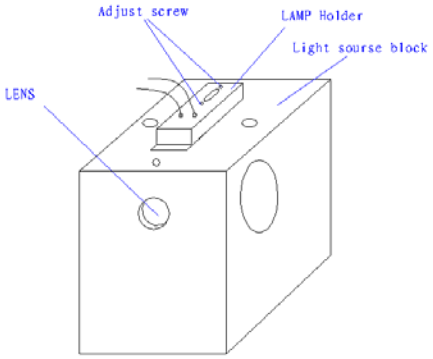


Figure 1.7

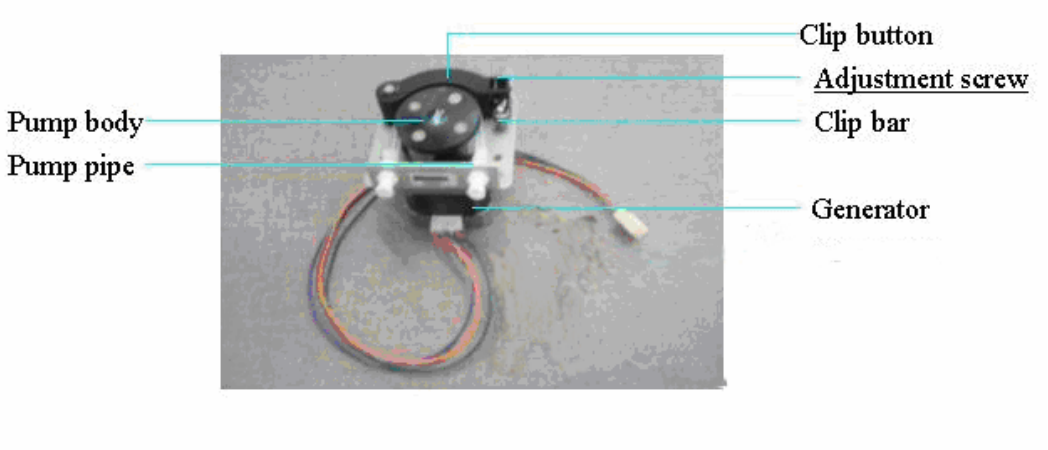
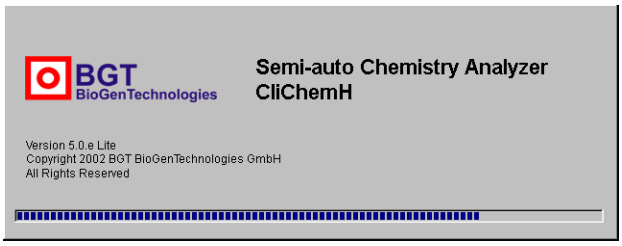

Clip button
Adjustment screw
Pump body
Clip bar
Pump pipe
Generator

Figure 1.8

Chapter 2 Operating Procedures

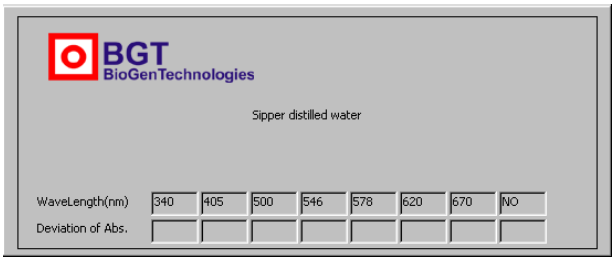
2.1 Powering on

Turn the instrument on using the power switch on the rear panel. The screen will display the following:



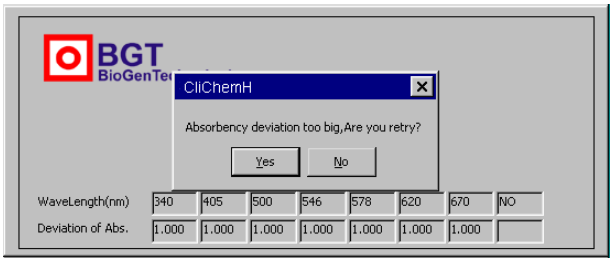
Screen 2.1 System initialization

The instrument will be waiting the lamp stable in 2 minutes. Then the screen will display as following:



Screen 2.2

Raise a test tube of distilled water up to the aspiration tube press **Rinse** key to rinse the flow cell for about 20 seconds then press the “Sample Button” to aspirate the distilled water. After you hear the control unit valve cycle, remove the tube. The semi-auto chemistry analyzer will now read and save the absorbance reading for water for all seven filters in the machine. If the absorbance reading is too high or too low, the following screen will displayed



Screen 2.3

Select “No”, the system will ignore the deviation above and move to test menu. Select “Yes”, and raise the test tube of water up to the aspiration tube, and press **Rinse** to rinse the flow cell. After a few seconds, press **Rinse** again to stop the

rinse, and then press the “Sample Button”. If the above screen still displayed, contact the supplier.

2.2 Basic operating

2.2.1 Mouse

The instrument has different configure for different version.

- CliChemH plus: has a special mouse designed for PDA or instruments
- CliChemH lite: Normal mouse for PC (USB interface)

2.2.2 Keyboard(option)

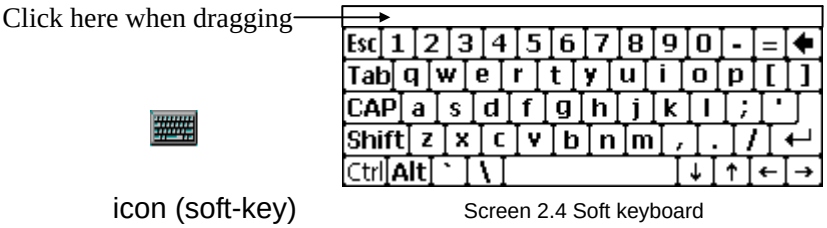
Connect the ext. Keyboard to the instrument when the analyzer powered off. You can use the keyboard just like to operating a PC keyboard.

2.2.3 Soft-keyboard

You can use the hot-key

Or the mouse to click the icon (soft-key) to pop a soft-keyboard, (Screen 2.5 Soft keyboard) and click the icon again, the soft-keyboard will be close.

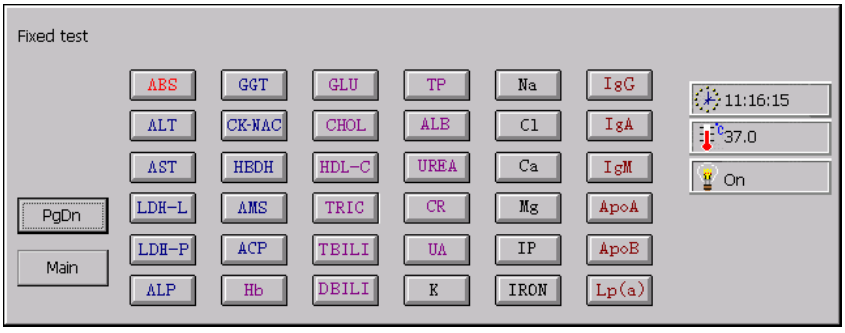
If you want to move the keyboard, please click the its upper blank area and drag it away.



Screen 2.4 Soft keyboard

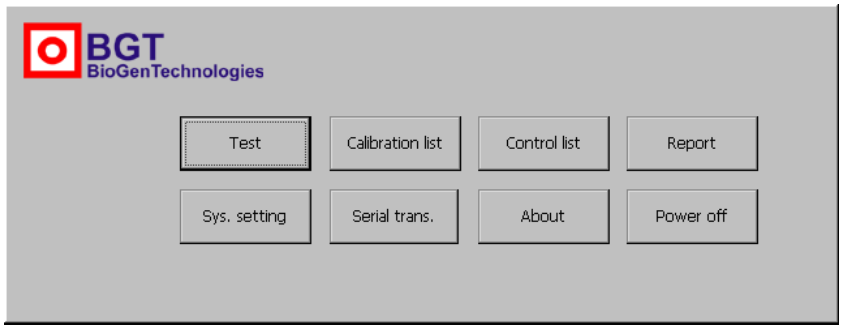
2.3 Main menu and system parameters setting

After the instrument initialization, the screen will display the following:



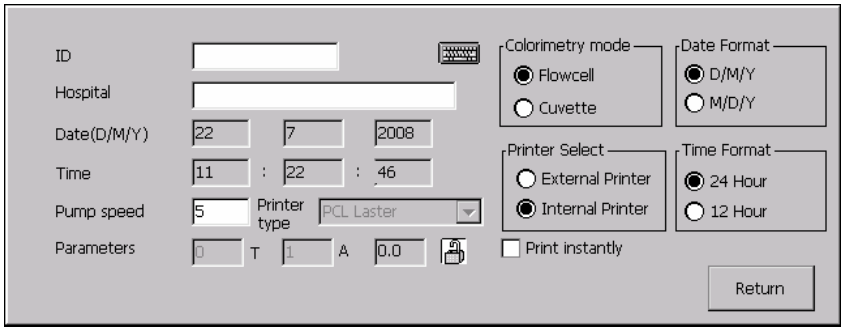
Screen 2.5 Test survey menus

Select “Main”, the screen will change to:



Screen 2.6 Main menu

Click “Sys Setting”,



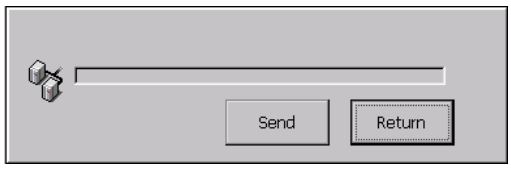
Screen 2.7 Sys setting menu

1) Setting time and date

2) Printer Select
   - Printer Inside: If you select “Printer Inside”, the Printer type can not be selected.
   - Printer Outside: If you select this, you need to select the printer type also.

3) Inputting the Hospital name

Select **“**Serial trans.**”,** the screen will display the following:



Screen 2.8 Serial transfer

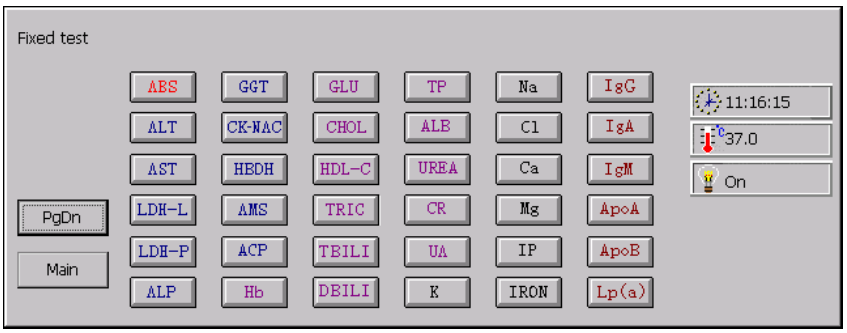
The test result in CliChemH can be transferred to Desktop PC through standard RS232 Cable; the serial port of PC should be set as following:
19200 baud, Even Parity, 8 bit of data and 1 bit of stop
Details of Protocol please see Appendix **II**:

2.4 Programming test parameters

CliChemH has a built-in menu of 130 assays. 47 assays of most commonly applied data reduction formulae are pre-programmed.

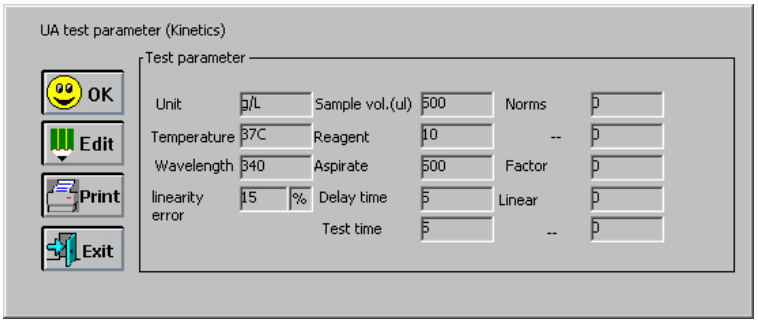
2.4.1 Modifying preprogram

Click “Test” button in main menu. The screen will display the following:



Screen 2.9 Test survey menus

1) Click the button which will be modified, such as “UA”, The screen will display the following:

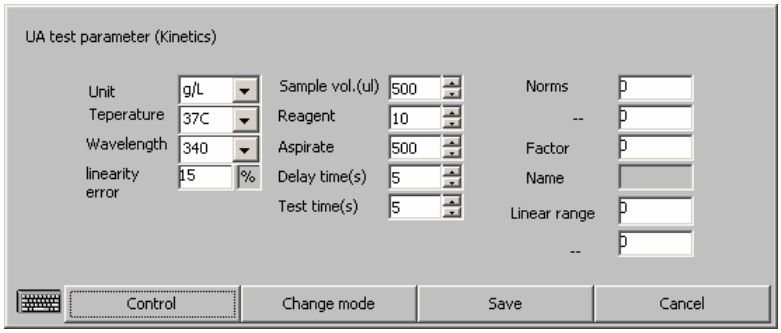


Screen 2.10 Test Enter menus

- Select “Edit” to modify the parameter of the test.

2) Modifying parameters

Note: the linear range should be input according to the reagent instruction.



Screen 2.11 Programming menu

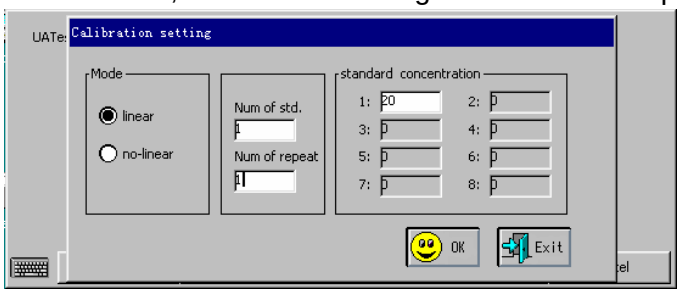
3) Click “Save” button to save the modification, or click “Cancel” to ignore.

2.4.2 Programming a new assays

1) Select a free button of assays by clicking “Pgdn” button, then click the button
2) Input parameters
3) Save the input

2.4.3 Calibration parameter

Select “Calibration”, “Calibration setting” window will be open.

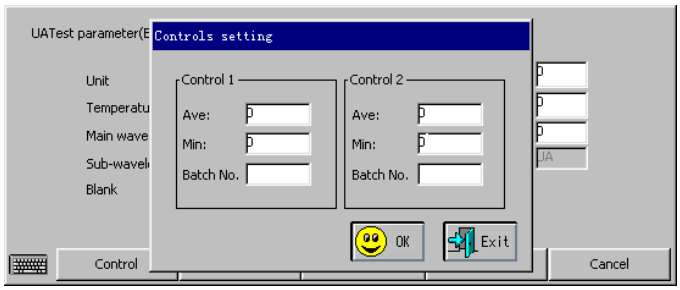


Screen 2.12 Calibration setting menu

1) Calibration for linear tests
   - Standard number means that how many standards will be measured. The measured results will be averaged. Input the number by clicking the window.
   - Repeat number: This parameter determines how many standards (with the same concentration) will be used for calibration. The results of multiple measurements will be averaged by the system.
   - Select “OK” to confirm the selecting.
   - Select “Exit” to go back to above menu with modify
2) Calibration for non linear tests
   - Standard number means that how many standards will be measured. The standards are different concentrations. The measured results will be a calibration curve. Input the number by clicking the window.
   - Repeat number: This parameter determines how many standards (with the same concentration) will be used for calibration. Possible inputs are 1, 2 and 3.The results of multiple measurements will be averaged by the system.
   - Select “OK” to confirm the selecting.
   - Select “Exit” to go back to above menu.

2.4.4 Control parameter

Select “Control” for programming control. The follow window will appear:

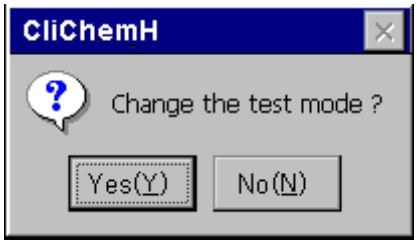


Screen 2.13 Controls setting menu

a) Control 1 and control 2: Two controls could be defined.
b) Mean value: Input the mean value of the control.
c) Minimum: Input the minimum of the control.
d) Batch number: The different batches of a control will have different values. Enter the batch number.
e) Select “OK” to confirm the programming. Select “Exit” to go back the above menu without modifies.

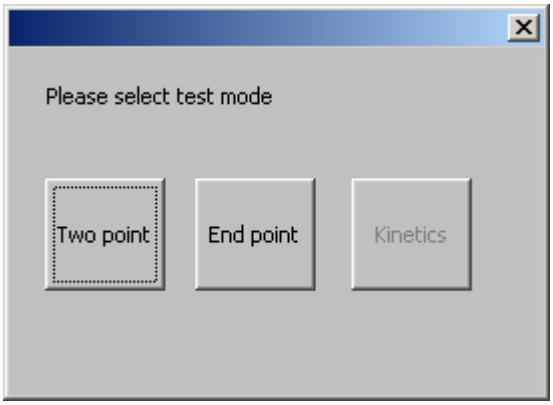
2.4.5 Selecting a Mode

Enter the menu of the “Programming” (screen 2.13), click “Change mode”. A window will be pop-up.



Screen 2.14 Measurement mode menus

Select “Yes”, the following screen appears:



Screen 2.15 Change mode menus

a) Endpoint

After a required incubation time, the reaction reaches its maximum color development, or it’s Endpoint. The color of the reaction will remain stable and constant for certain period of time. During this time a

measurement in Absorbance is taken.

b) Endpoint Bichromatic

Bichromatic is actually endpoint determination measured at two different wavelengths. The advantage is that some unwanted interference due to the color of the serum sample can be eliminated by subtracting the measurement done with the second wavelength filters. This can be done when you select a sub-wavelength in “Parameter change” menu. It was described in **2.4.1**.

c) Endpoint determinations against a standard Curve

d) Endpoint determinations against a Multi-standard Curve

This is a normal endpoint determination, in which linearity may not be perfect throughout the whole range that is interest. As a result it is calibration curve (a number of standards) instead of a single standard.

e) Kinetic

Kinetic determinations are tests whose enzyme activity is measured continuously over a certain period of time and finally referred to 1 minute.

f) Twopoint

After a pre-defined incubation time, two absorbance readings are taken at different and programmed time interval. From the delta absorbance between the two measurements the final result is calculated. Each of the measurements taken is a mean of a large number of readings taken in quick succession.

2.4.6 Save the Change

After select the measure mode, Select “Save change” to save the selection. The menu will change to the “test enter” menu. Select “Enter” to perform the test procedure.

2.4.7 Return

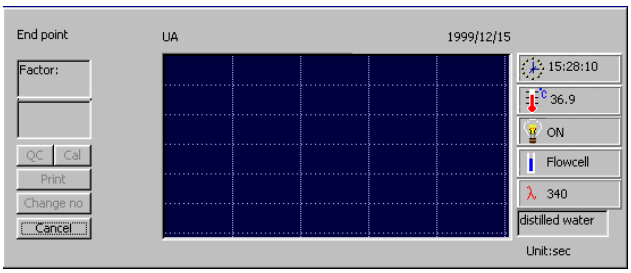
Select “Exit” to go back to the “test enter” menu.

2.5 Perform tests

Select the test to be performed in the menu of “test overview”, and select “OK” to go to the menu of “test procedure” in the menu of “Test enter”.

2.5.1 Test procedure menu

The menu of “test procedure” is displayed as following:

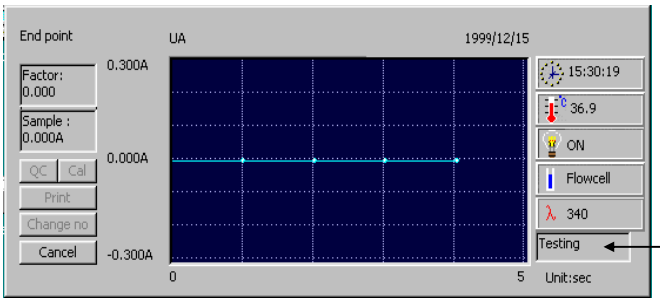


Screen 2.16 Test procedure menus

1) Factor window: Factor
2) Result window: Test result
3) Control: Perform the control test.
4) Calibration: Perform the calibration test.
5) Print: Print the test result.
6) Change No.: Change the sequence number tested.
7) Time: Display the time.
8) Temperature: Display the temperature of the flow cell.
9) Lamp: Show the status of the lamp: On/Off.
10) Wavelength: Show the wavelength selected.
11) Instruction window: Display the instruction information.
12) Return: Return back to above menu.
13) Reaction window: A curve will be displayed to represent the reaction.

2.5.2 Perform

Follow the instructions displayed on the “instruction window”.



Screen 2.17

1) Instruction window: **Aspirating distilled water**
Put a tube with distilled water under the sample tube and press **Sample key** (figure 1.4).
The measure result will be displayed on the “result window” and on the “reaction window”.

2) Instruction window: **Aspirating reagent blank** or **Aspirating Sample Blank,** Hold the reagent blank or sample blank under the sample tube and press **Enter** key or sample button, the programmed solution will be

aspirated and measured. The process and result of the measurement will be displayed.

3) Instruction window: **Aspirating Sample**
   Hold the sample under the sample tube and press **Sample button**. The programmed solution will be aspirated and measured. The process and result of the measurement will be displayed.

4) Calibration: will be described in **Chapter 3**

5) Control: will be described in **Chapter 4**

2.5.3 Changing test

When changing over from one test to another, washing of the flow cell is required, to prevent reagent carry over, causing wrong calibration and measurement result.

To wash the flow cell:

- Place a container of distilled water under the sample tube. Press **Rinse** key. The aspiration/flow cell system will be washed continuously now, until the **Rinse** key is pressed again. Let the flushing continue for about 30 seconds.
- Go back to the “Fixed test” menu; the new assay can be started now.

Chapter 3 Calibration by standard

3.1 General

Certain tests require calibration by 1 or more Standards. Calibration results are stored in the flash memory of the analyzer and can be used again for future measurement.

Calibration can be programmed and subsequently done for different measurement mode: Endpoint or Twopoint. For Endpoint, the calibration could be with/without Reagent Blank and/or Sample Blank. For Twopoint, the calibration could only be with or without Reagent Blank.

The calibration by standard should be performed depending on the stability of the reagents, batch of the reagent, and type of test. The new ones will overwrite the previous calibration data in the flash memory.

3 procedures should be performed for the calibration by standard:

- Program calibrations
- Measurement of calibrations
- List calibrations

3.2 Program calibration

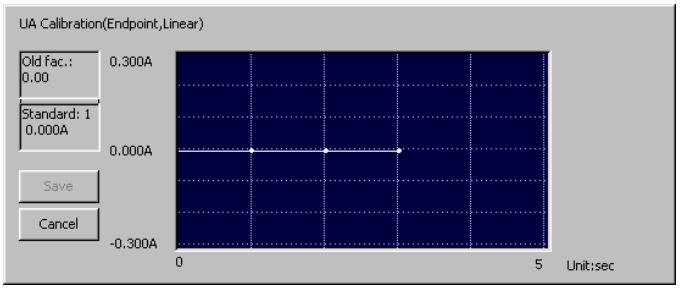
The calibration parameters could be programmed in the menu “parameter modify”, see the screen 2.14. The setting was described in **2.4.2**.

3.3 Perform linear tests

For linear tests, the relation between Absorbance and Concentration is a (linear) straight line. This type of test is normally calibrated with one or more standard(s) of 1 concentration and with or without Reagent Blank.

The calibration can be run at any time during a test run, after the test has been selected. Select “Calibration” in menu of “test procedure”:

1) Instruction window will appear: **Standard “#”**
   Hold the standard sample “#” under the sample tube and press **Sample button**. The programmed volume will be aspirated and measured. The process and result of the measurement will be displayed.
2) Instruction window: **Standard “#”, Repeat #**
   Following the instruction of the “instruction window”.



Screen 3.1

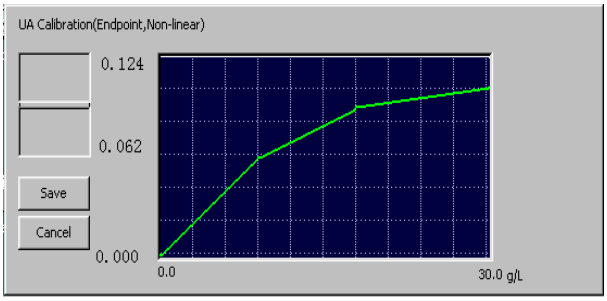
3) The result will be displayed on the result window, and the standard curve will be displayed in same time. User can save and print the result

3.4 Perform the calibration of non linear tests

Non linear tests are those tests where the relation between Absorbance and Concentration is not linear. These tests are normally calibrated on more than 1 standard of different concentrations. The analyzer has a special arithmetic to link the calibration points to a calibration curve. The measurements for patient or controls are then interpolated automatically depending on the curve.

The calibration can be run at any time during a test run, after the test has been selected. Select “Calibration” in menu of “test procedure”:

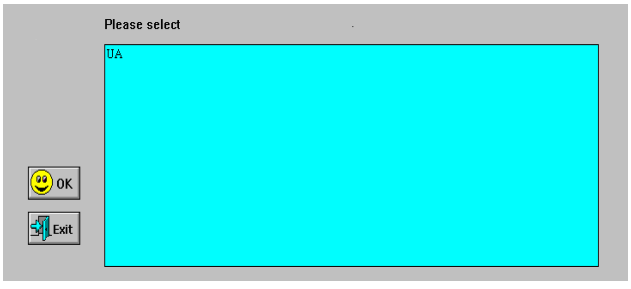
1) Instruction window will appear: **Aspirating Standard “#”**
   Hold the standard sample “#” under the sample tube and press **Sample button**. The programmed volume will be aspirated and measured. The process and result of the measurement will be displayed.
2) Instruction window: **Aspirating Standard “#”, Repeat #**
   Follow the instruction of the “instruction window”.
3) The result will be displayed on the result window, and the standard curve will be displayed in same time. User can save and print the result.



Screen 3.2

3.5 List calibration

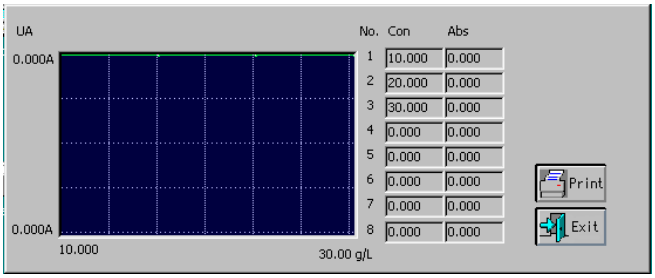
Select “**Calibration list**” in “Main menu”, to list the calibrations. The list screen will be displayed:



Screen 3.3

1) Select the test which one will be checked. Click “OK”.

2) The result of the test will be displayed on the screen:



Screen 3.4

3) Print the result by selecting the “Print”.
4) Select “Exit” to go back to the above menu.

Chapter 4 Control

4.1 General

The control program gives the possibility of storage and statistical evaluation of controls measured on the instrument.

For all 130 tests programmed in the unit, 2 controls can be defined. The result of controls for 130 tests of 365 days could be stored automatically. 3 operating should be performed for the controls:

- Program controls
- Measurement of controls
- List statistics

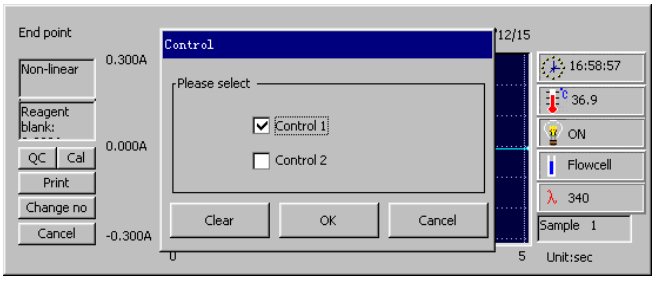
4.2 Program controls

The control parameters could be programmed in the menu “parameter modify”, see the screen 2.15. The setting was described in **2.4.3**.

4.3 Measurement of controls

A control can be run at any time during a test run, after the test has been calibrated.

Select “Controls” in menu of “test procedure”, a window will be open as following:



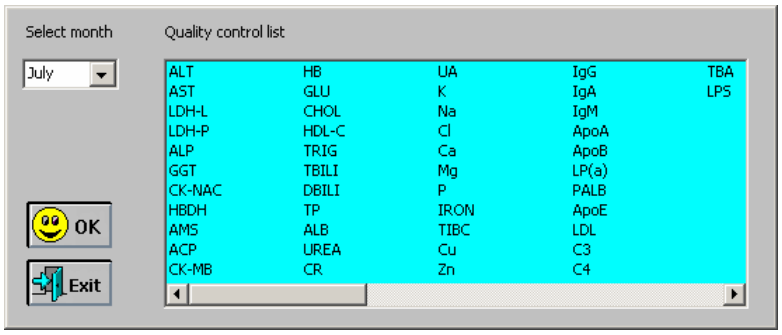
Screen 4.1

1) Choice “1” if only measuring 1 control, and choice “2” if 2 controls will be measured. Select “Enter” to confirm the choice.
2) Instruction window will display: **Control “#”**
   Hold the control requested by analyzer under the sample tube and press **Sample button**. The programmed volume will be aspirated and measured. The process and result of the measurement will be displayed.
3) The result will be added to the statistical memories automatically. The evaluation of control results can be accessed through the main menu and described in **4.4**.

4.4 List controls

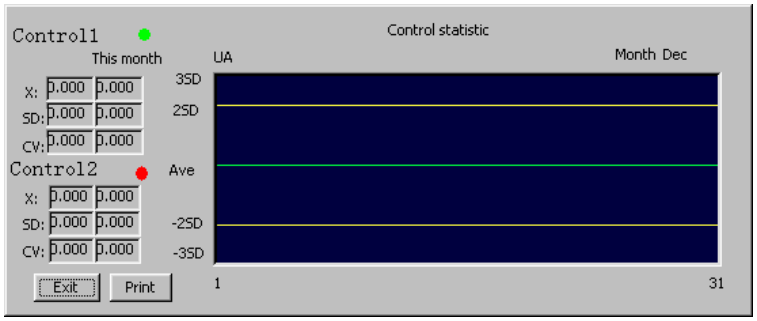
Select “Control” in main menu, to list the statistics of controls. The list screen will

be displayed:



Screen 4.2

1) Select the test and the month will be checked. Click “Enter”.
2) The statistic of the controls will be displayed on the screen:



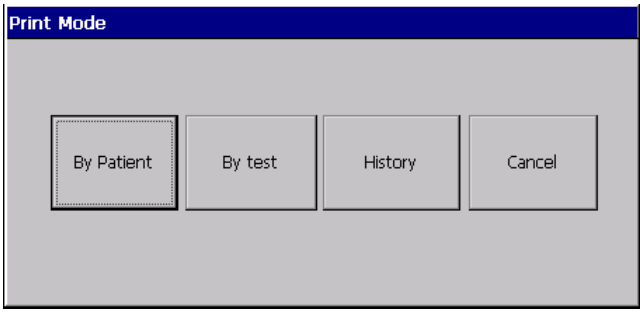
Screen 4.3

3) Print the result by selecting the “Print”.
4) Select “Exit” to go back to the above menu.

Chapter 5 Report

5.1 Summary

In this part, three report styles are provided: “By patient”, “By test” and “History”, you can select one style from four according your requirement.



Screen 5.1

5.2 Print by patient

In the state of Screen 5.1, select “By patient”, a new window will be open.

Operation guide:

1. Update patient information

Select one patient, the correspondent line is activated. Input name, department, age and sex, click “Update”, then the patient information is change into what you have input.

2. Add a patient

If you want to add one or more new patients, you can click “Add” after the patient information has been input. Each new patient wills a different patient NO. If you want to test the patient’s sample, just change the present sample No. into the patient No.

3. Select print mode

In this part, seven print modes are provided, “General”, “Liver function”, “Kidney function”, “CK enzymes”, “Lipids”, “Iron” and “Electrolytes”.

General: Print all item tested in the test order.

Liver function: If this mode is selected, 18 items are included.

1 ALB
2 TP
3 GLB
4 ALB/GLB
5 T BILI
6 D BILI

7 I BILI
8 AST
9 ALT
10 AST/ALT
11 GGT
12 ALP
13 LDH
14 LDH/AST
15 GGT/AST
16 TBA
17 PALB
18 GLU

Kidney function: If this mode is selected, 6 items are included.

1 UREA
2 CR
3 UA
4 TP
5 ALB
6 GLU

CK enzymes: If this mode is selected, 4 items are included.

1 CK
2 CK-MB
3 AST
4 LDH

Lipids: If this mode is selected, 8 items are included.

1. CHOL
2. TRIG
3. HDL-C
4. HDL-C
5. ApoA
6. ApoB
7. ApoA/ApoB
8. ApoE

Iron: If this mode is selected, 2 items are included.

1 IRON
2 TIBC

Electrolytes: If this mode is selected, 11 items are included.

1 K
2 Na

3	Cl
4	Ca
5	Mg
6	P
7	Cu
8	Zn
9	GLU
10	AMS
11	LPS

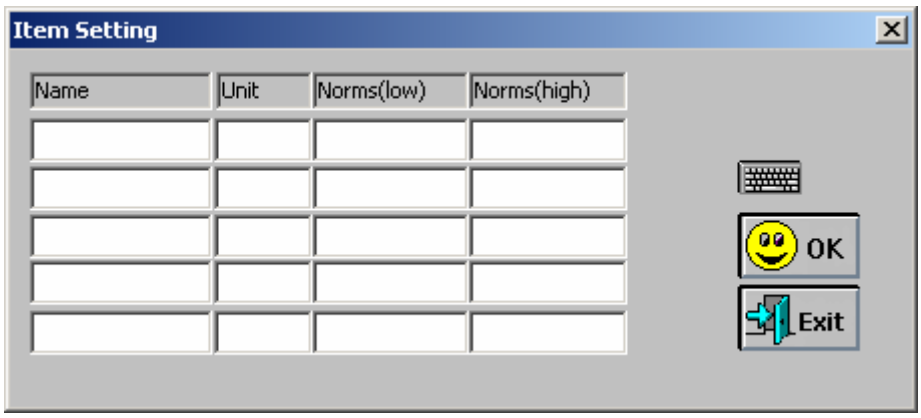
Input patient NO which need to be printed, patient NO can be input as following:

1. 3, 6
1. 1-5
2. 1-4,5-6
3. 3,4,5-7
4. If all patients need be selected, you can select the check box “select all”

Click “Print”, the report will be printed. If some item in the mode hasn’t been tested, there will have no correspondent data in the report.

4. Input no-chemistry item

Setting: Directly inputting a no-chemistry item and result is also permitted, this item will be printed in the “General” mode report. In the window of “By patient”, click “setting”, a window will be open as Screen 5.2. “Test name”, “Unit”, “Normal (low)” and “Normal (high)” are all need to be input, and each can’t be longer than eight characters. All the no-chemistry items will be saved if RT-1904 is closed correctly.



Screen 5.2

Edit: In the window of “By patient”, select one patient line, and then click “setting”. In the “Item edit” window, input no-chemistry item result, this item will be printed in General mode report.

5.3 Print by test

In the state of Screen 5.1, click “By test”, a new window will be open.
Select the Item to be printed, then click “Print”, all test result of selected item will be printed. If you want print all items, just select the “Select all” check box.

5.4 History records

In the state of Screen 5.1, click “History”, a new window will be open.
CliChemH can store 3500 pieces of records at most. In the new window, drag the scroll bar, you can see about all test results of history.
During the operation of print, delete and data transfer, click "Select all" check box, you can do the operation on all records. Input the order number of patient, you can do the operation on selected records.
Patient No. can input as following:

1. 3,6
2. 1-5
3. 1-4,5-6
4. 3,4,5-7

Chapter 6 Remote service

CliChemH Lite Version can’t support the remote service!

Chapter 7 Close system

At the end of the working, you must perform the Closing procedure by selecting “Power off” in the “Main menu”.

1) The system will store the parameters and the results of tests.
2) The screen will display “aspirating distilled water”.
3) Place a container of distilled water under the tube. Press **Sample button**, Rinse will take few minutes
4) The screen will display “ Turn off the System”
5) Turn off the power.

ATTENTION! Cautions

Never power off the system without performing the closing procedure. It will cause that lost of the data and influence the measurement.

Chapter 8 Maintenance

8.1 General

The CliChemH is a Clinical Semi-auto Chemistry Analyzer, which requires only a minimum amount of maintenance.

Some general maintenance is necessary to keep the instrument in an optimal condition.

8.2 Cleaning the outside

Always keep the outside of the instrument clean and free dust. You can wipe the outside with a damp (not wet) cloth and a mild detergent

Wipe the display screen with a soft, nonabrasive cloth.

ATTENTION! Cautions

Do not use any type solvent, oil, grease, silicone spray, or lubrication on the instrument.

8.3 Clean procedure for the flow cell

The inside of the flow cell should be kept as clean as possible, to assure good and reliable measurements.

To keep the inside clean, follow the following procedures:

8.3.1 Washing when Changing tests

When changing over one test to another, some washing of the flow cell is required.

To wash the flow cell:

- Place a container of distilled water under the tube. Press **Rinse** key. The flow cell system will be washed continuously now, until the **Rinse** key is pressed again. Let the flushing continue for about 2 minutes.

8.3.2 Washing twice a day

The following procedure is needed twice a day, to wash out those residues from the wall of the flow cell, which cause bad filling of the cell:

- With the solution of neutral detergent (such as Tweenum 20). Let the neutral detergent stay in the flow cell for 2-3 minutes. The distilled water added some detergent is better. The ratio of the detergent is depending on the detergent used. Normally a 1-5% solution is adequate.
- Rinse with distilled water without detergent for about 1 minute.

8.3.3 Closing the system by the closing procedure

At the end of the working, you must perform the Closing procedure by selecting “Closing system”.

1) The system will store the parameters and the results of tests.
2) The screen will display “distilled water”.
3) Place a container of distilled water under the tube. Press **Sample button**, Rinsing will take few minutes. Leaving the distilled water inside the flow cell.
4) The screen will display “ Turn off the System”
5) Turn off the power.

ATTENTION! Cautions
Never leave Sample/Regent inside the flow cell for a long period of time.

8.4 Replacement the lamp

8.5 Replacement of the internal tubing

8.6 Replacement the fuse

The fuse is situated at the rear side of the analyzer. It is mounted in the fuse holder beside the power switch. Pull out the fuse holder lid and the fuse can be replaced easily.
Replacement fuse should be the following rating:
Fuse rating: **250V, 3.15A**

ATTENTION! Cautions
Never mount fuse of wrong rating!

8.7 Trouble shooting

1)	The analyzer could not power on	--- Check the power cord --- Check the fuse --- Check AC power
2)	The lamp couldn’t turn on	--- Check the connector of the lamp --- Change the lamp
3)	Not Print	--- Check the setting Check the cable --- Assure that printer powered on firstly.

4)	Non aspiration of sample	---	Check the pump tube
		---	Check tube pipeline
		---	Rinse and check the flow cell
5)	The result of water blank is too high	---	Check the lamp
		---	Change the distilled water
		---	Rinse the flow cell
6)	Repeats are not good	---	Check if there is air bubble in flow cell
7)	Controls out of the target	---	Reagent validity
		---	Assure the program is correct.
		---	The quality of controls
		---	To test again by changing the mode
		---	Check the flow cell and select a new reagent and control
8)	The aspirate volume not stable	---	Liquid system blocked, Rinse the Tube pipeline, or change the tube.

8.8 The instrument's disassembly

If the user meets some problems and needs to open the instrument, you can do as follow:

1) Turn over the instrument.
2) From bottom of the instrument you can see seven plastic pillars with screw hole. Uses a screwdriver unscrew these seven screws. (Figure 8.1)
3) Turn the instrument back to normal position.
4) Set the LCD screen to vertical position. (Figure 8.2)
5) Lift the top cover of instrument gradually, and open the front side about 3 inches first. Do not use too much force, because there are cables between top and foot cover.
6) After open the machine, you can see the inside distribute of top and foot cover like figuer8.3
7) Find the LCD connector on the main board, and open it carefully.
8) Then turn over the top cover, disconnect 5 other cables

Set up the machine in reverse order.

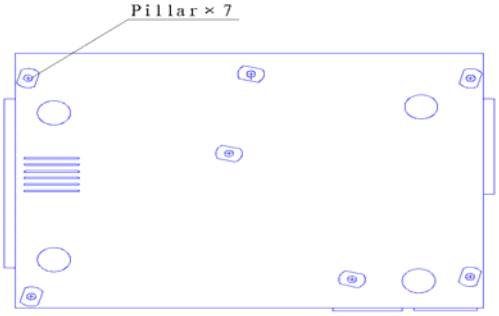


Figure 8.1

Figure 8.2

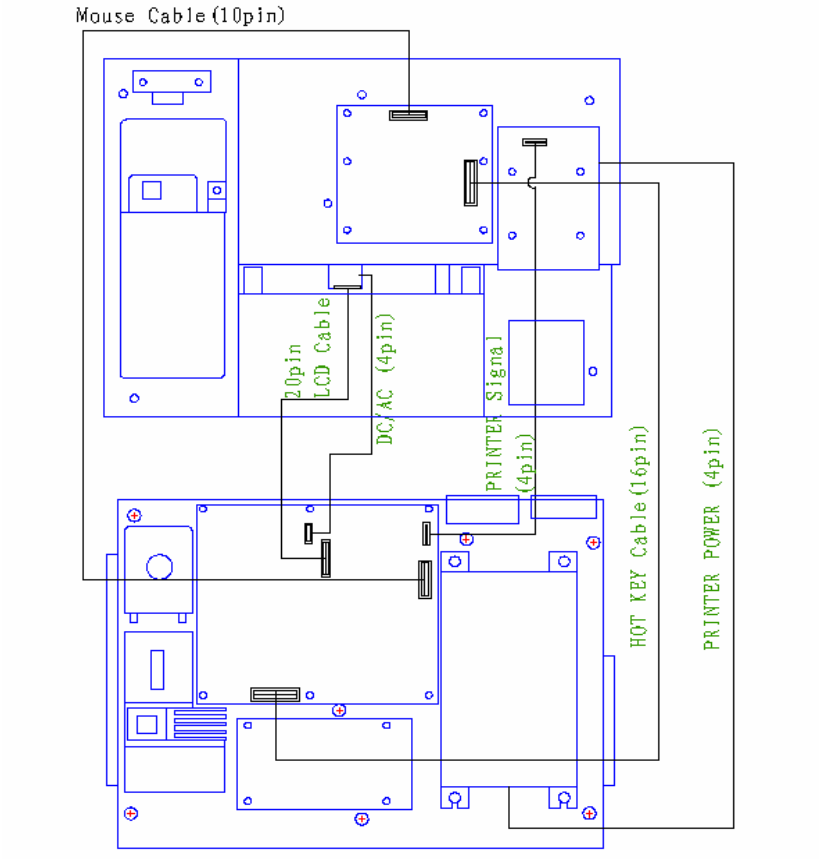


Figure 8.3

Appendix I: General Specifications

Weight:	**10 kg**
Dimension:	**450mm (L) x330mm (W) x140mm (H)**
Power supply:	**90-250VAC, 50/60Hz**
Power consumption:	**150 W max**
Fuses:	**3.15A, slow-blow type 5x20mm**
Operating condition:	**15°C to 32°C; RH 85% max**
Storage condition:	**-20°C to 50°C; RH 85% max**
Display:	**7” color LCD (640x240, 256 colors)**
Measurement range:	**0.000-2.500 abs**
Resolving power:	**0.001 abs (display), 0.0001 abs (calculation)**
Interference filters:	**340nm, 405nm, 500nm, 546nm, 578nm, 620nm, and 670nm**
Half band width:	**<10nm**
Lamp:	**Tungsten halogen lamp 6V/10W**
Temperature control:	**Peltier. 25°C, 30°C, 37°C ±0.1°C and ambient temperature**
Flow cell:	**30ul quartz flow cell.**

Appendix II: Serial Connection protocol

1. Serial port state

Data is transmitted at 19200 baud,
With 1 stop bit
8 data bit and Even Parity

2. Message format

The initial parameter must be the capital letter “R”, each line consists of 12 data in following order:

Parameter	**Possible values**	**Space mark**
Initial parameter	“R”	,
Patient name	Character or NULL	,
Department	Character or NULL	,
Sex	Character or NULL “0” = Male “1” = Female	,
Patient No.	Character	,
Name of test	Character	,
Result	Character	,
Units of measurement	Character	,
Checksum	Character	

Checksum = All of parameter + All of space mark

3. Send over

CliChemH sends a character string “TRANSFER FINISH”, when the task has been completed.

Example:
R, Biachi, 0, 43, 1, TP, 136.00, g/L, 0794
R, Rossi, 1, 40, 2, TP, 147.00, g/L, 0765
R, Tony, 0, 6, 3, TP, 35.00, g/L, 069d
TRANSFER FINISH